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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,667	08/27/2001	Jens Petersen	60117.000006	2505

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,667	PETERSEN, JENS	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/11/08, 7/11/08 and 8/06/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-128* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request of request for extension of time, amendment, remarks and 1.132 declarations by Dr. Diamond and Mr. Lessel, all filed 6/11/08; signed declaration by Dr. Ankorina-Stark filed 7/11/08 and 1.132 declaration by Dr. Dmochowski filed 8/06/08. Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 are canceled; new claims 91-128 are added and are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

The Claims :

Claims 9-17, 29-32, 34-38, 52, 53, 62, 67-69, 78-80 and 82-90 have been canceled. Claims 91-128 have been added. Claim 91 is drawn to method of treating urinary incontinence, the method comprises increasing resistance of passage through a urethra by "administering prosthetic device into the urethra" the prosthetic device comprises "hydrogel, comprising about 0.5 to 25% by weight based on the total weight of the hydrogel," the polymer is prepared by a method comprising combining acrylamide and methylene bis-acrylamide: wherein the "hydrogel includes less than 50 ppm monomeric units, has a complex viscosities of about 2-50 Pas and has an elastic modulus of about 1-200 Pa."

"Prepared by a method … bis-acrylamide," is the process of preparing the acrylamide hydrogel. "Less than 50 ppm monomeric units" in the hydrogel represent residual amounts of the starting acrylamide monomer and the cross-linker methylene bis-acrylamide. The viscosity and the elastic modulus are inherent properties of the hydrogel.

Claim 111 is similar to claim 91 except that the method provides "adequate resistance in a urethra by bulking the urethra" by "administering prosthetic device into the urethra." "Adequate resistance" is relative and given to artisan's judgment of what is adequate.

Claim 115 is similar to claims 91 and 111 except that a bulking agent, which is hydrogel prepared from acrylamide and bis-acrylamide and comprising pyrogen free water or saline solution 0.5% to 25% by weight of a polymer based on the total weight of the hydrogel is injected.

Claim 116 is similar to 115 except for omitting the phrase "bulking agent" and starts out by reciting injecting a hydrogel into a urethra.

Claim 117 is similar to claim 115 except a prosthetic device that comprises about 0.5 to 25% by weight of a polymer based on the total weight of the hydrogel and prepared by … is administered into the urethra to bulk the urethra.

The common thread connecting independent claims 91, 111, 115, 116 and 117 is that the same hydrogel composition is administered into the urethra by broad administration term or specific injection mode of administration; the administered hydrogel composition functions to treat urinary incontinence by bulking the urethra or increasing resistance to passage of urine through the urethra; With the function attributable to the properties/characteristics of the polyacrylamide hydrogel.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. New claims 91-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041) according to the rejections of record and modified to reflect the new claims as reiterated herein below.

New generic claims 91, 111, 115-117 are analyzed above as described under "**The Claims**:" It is noted in the analysis for claim 91 that the method of treating urinary incontinence comprises administering to the urethra. Claim 111 treats urinary incontinence by administering the hydrogel to bulk the urethra. Claim 115 injects the hydrogel into the urethra to obtain bulking; claim 116 injects the hydrogel into the urethra. Claim 117 administers the prosthetic device comprised of polyacrylamide hydrogel into the urethra to obtain bulking of the urethra. Increasing the resistance of the urethra and bulking are intended uses of the hydrogel derived from the properties/characteristics of the hydrogel. The other aspects of the properties of the hydrogel as described for claim 91 is the same for the claims 111 and 115-117.

Pavlyk discloses cross-linked polyacrylamide hydrogel (claims 109, 110 and 123) produced from acrylamide and methylene bis-acrylamide monomers and apyrogenic or pyrogen

free water (abstract; Table 1) meeting the limitations of the acrylamide hydrogels and pyrogen free water of the claims 92-96, 118-120 and 123; the hydrogel is used as endoprosthesis by way of sterile injections into tissues by way of canals of the corporum cavernosum (column 1, lines 5-10; column 10, lines 37-56). Pavlyk discloses that the hydrogel provides bulking (column 3, lines 17-18) meeting the characteristic and intended uses of claims 91, 111 and 115-117; the hydrogel of Pavlyk has low viscosity (column 2, lines 58-67) and the Pavlyk hydrogel would inherently have the viscosity properties recited in the claims. The amount of the acrylamide in the hydrogel ranges from 3.5 to 9.0% touching pints along the claimed acrylamide range of 0.5 to 25% as in the generic claims 91, 111 and 115-117. The hydrogel of Pavlyk would inherently exhibit the intended use of the claimed hydrogel and would have the claimed properties since a product and its properties cannot be separated and thus meets claims 95, 105, 106, and 112-114. The 3.5% acrylamide of Pavlyk is less than 15%, 10%, 7.5%, 5% (meeting claims 94, 100-102) and 3.5% is at least 1%, 1.6% (meeting claims 94 and 104). The amount of water or aqueous solution in Pavlyk ranges from 88% to 96% (see Table 1) meeting the water limitation of claims 96, 118, 120, 121 and 126 and Pavlyk's use of pyrogen free water meets the use of pyrogen free water in the claims. Since the reaction between the acrylamide monomer and the methylene bis-acrylamide monomer cross-linking agent goes to completion, since the Pavlyk reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Pavlyk renders less than 50 ppm monomeric unit obvious.

While Pavlyk discloses injecting the hydrogel into caverns that may meet canals or conduits or channels, and if the cavern does not specifically read on channels or tubes, it is

known according to the RU reference 2,148,957 and as admitted by applicant that the polyacrylamide hydrogel, "a gel within the scope disclosed by Pavlyk" is injected into the ostium of the ureter to impede the flow of urine (see paragraph of remarks filed 2/27/06 and first full paragraph on page 10 of remarks filed 10/08/07), with injecting meeting claims 115 and 116 Furthermore, it is known in the art that urinary incontinence is treated by administering prosthetic device comprising polyacrylamide hydrogel into the urethra (Annis at abstract; column 2, lines 65-68; column 3, lines 12-23). Regarding new claim 127, stress, reflex and urge incontinence are form of urinary incontinence as evidenced by Gale Encyclopedia of Medicine, Dec. 2002 under Urinary Incontinence. Regarding new claim 128, the submucosa is part of the urethra. Therefore, it would have been obvious to one of ordinary skill in the art to inject hydrogel into the caverns that would inherently act as a bulking agent or increasing the resistance of passage of urine through the caverns. One having ordinary skill in the art would have been motivated to inject the acrylamide hydrogel into the ostium of the ureter or into the urethra with the expectation that the hydrogel would act as a bulking material that would create increased resistance to the flow urine in the urethra or the ureter that would lead to the treatment of urinary incontinence.

Response to Arguments

3. Applicant's arguments filed 6/11/08 have been fully considered but they are not persuasive.

4. Applicant argues that Pavlyk does not disclose polyacrylamide that meets the limitation of the acrylamide hydrogels of the claims and that Mr. Lessel has determined that the acrylamide hydrogels of Examples 1-3 of Pavlyk have residual monomeric acrylamide of 1278 ppm, 2646

ppm and 693 ppm respectively, which are larger than the 50 ppm limit required by the claims. The examiner disagrees with applicant's position and the declaration by Mr. Lessel with be addressed latter. The claimed method uses polyacrylamide hydrogel product which is prepared by reacting acrylamide and methylene bis-acrylamide. While the product used in method reads on any polyacrylamide hydrogel, the polyacrylamide hydrogel product prepared by bringing together acrylamide and methylene bis acrylamide does not indicate how much of the acrylamide and methylene bis acrylamide are used in the reaction or are reacted to arrive at the hydrogel of the claims. Thus, the hydrogel product formed is a broad hydrogel composition in terms of how much of the acrylamide and how much of the methylene bis acrylamide are reacted together. The Examples in Pavlyk are directed to specific embodiments and applicant's analysis of the hydrogel of Examples 1-3 ignores the broad disclosure of Pavlyk in which various combinations of acrylamide and methylene bis acrylamide are contemplated; it is noted that prior art is not limited by its examples.

5. Applicant further argues that Annis is unrelated to the use of polyacrylamide as a bulking agent and cannot therefore render the examined claims obvious because the solid prosthetic device is designed to elevate the bladder from the pelvis and not administered to the urethra. The examiner disagrees because while in the Annis reference, the device is located around the urethra, it is noted that the rejection is not an anticipatory rejection so that the combination of the references suggests the use of polyacrylamide hydrogel for use as bulking agent in the urethra (see the RU reference and applicant's admitted prior art in the remarks filed 2/27/06). Furthermore, the teaching by Annis that prostheses device comprised of polyacrylamide

hydrogel is used to treat incontinence or stress incontinence suggests that Annis is related to treating urinary incontinence using polyacrylamide hydrogel

6. Applicant has further relied upon the declarations of Dr. Ankorina-Stark, Dr. Diamond and Dr. Dmochowski to argue the point that Pavlyk in view of the other references cannot not render obvious the examined claims. The examiner disagrees with the declaration for the reasons in the declarations and those issues within the declarations will be addressed in a different section below.

7. Applicant also argues that the ordinary skilled artisan would not have been motivated to use acrylamide hydrogel as a bulking agent; and that the RU reference Sknar, in particular, would not motivated the use of acrylamide hydrogel as a bulking agent. The examiner disagrees because the use polyacrylamide gel as a bulking agent in the claims is the intended use of the hydrogel and the bulking of the urethra after administration of the hydrogel results from the characteristics/properties of the hydrogel so that the polyacrylamide hydrogel of the prior art when administered would inherently bulk the urethra.

8. Claims 91-128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogel et al. (US 6,335,028) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041) according to the rejections of record and modified to reflect the new claims as reiterated herein below.

Vogel discloses method of treating urinary incontinence by administering, by injection into esophageal wall or via the urethra and into the wall of the bladder sphincter and urethral wall, acrylamide based hydrogel produced with about 25 to about 98% methacrylamide and

about 2-about 50% methylene bis-acrylamide and containing autologous cells (abstract; column 4, lines 31, 32, 51-67; column 6, lines 1-16; column 10, lines 40-44; Examples 1 and 2); sterile and pyrogen free injectable solutions are employed for the storage of the hydrogel product (column 6, lines 58-60). Since the Vogel reference does not disclose the presence of residual monomeric units in the acrylamide hydrogel, and since the residual monomer in the product is expected to be very minimal if any, Vogel renders less than 50 ppm monomeric unit obvious.

Vogel discloses injectable acrylamide based hydrogel, and being injectable, it would have inherent viscosity that is characteristic of injectable hydrogels such as the claimed viscosities. The hydrogel contains cells (column 4, line 57) or other active agents (column 10, lines 54-67). The viscosity and modulus of elasticity are properties of the hydrogel. The amount of the polyacrylamide would approximate the amount recited since the starting amount of the acrylamide is at about 25% and the expected amount of the end product would be less than the starting 25%. Vogel does not state that the hydrogel is prosthesis. But it is known that acrylamide based hydrogels are used as endoprosthesis for administration into the ostium of the ureter for impeding the flow of urine according to RU 2148957 and applicant's admission (interview of 2/23/06 and remarks filed 2/27/06 and page 10 of remarks filed 10/08/07) and further that Annis discloses treating urinary incontinence by administering prosthetic device comprising polyacrylamide hydrogel into the urethra (abstract; column 2, lines 65-68; column 3, lines 12-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject the cross-linked polyacrylamide based hydrogel of Vogel through the urethra to treat urinary incontinence. One having ordinary skill in the art would have been motivated to administer the hydrogel of Vogel as a prosthetic device according to the

teachings of Annis, the RU reference or applicant's admitted prior art with the expectation bulking the urethra to treat urinary incontinence or impeding urine flow.

Response to Arguments

9. Applicant's arguments filed 6/11/08 have been fully considered but they are not persuasive.

10. Applicant argues that one having ordinary skill in the art would not be motivated to administer the hydrogel of Vogel as a prosthetic device according to the teachings of the references. The examiner disagrees. The references, for example, the RU reference is relied upon for showing that polyacrylamide hydrogel can be used as endoprosthesis; applicant's admitted prior art was relied upon for saying that the polymer of RU has been known to be used in impeding flow of urine.

11. Applicant referred to the declaration by Diamond that says that a person of skill in the art would not presume or reasonably expect that using a bulking agent to correct vesicouretic reflux would predictably be successful in treating urinary incontinence. The declaration by Diamond will be addressed below with the rest of the declarations. But, because vesicouretic reflux occurs as a result of decreased resistance where urine refluxes back into the bladder, it would be expected that administering polyacrylamide hydrogel into the urethra would successfully provided that resistance needed to impede urine flow.

Declarations under 37 CFR 1.132

A. Robert Lessel:

12. The declaration under 37 CFR 1.132 filed 6/11/08 is insufficient to overcome the rejection of claims 91-128 based upon 35 USC 103 over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041) as set forth in the last Office action because:

The data provided by the declarant Lessel considered on the examples while the disclosure is ignored. A reference is not limited by its working examples for what it teaches those of ordinary skill in the art. Furthermore, it is noted that claim 91 for example, says that %weight of the polymer is in the range of 0.5% to 25% and in the Pavlyk reference, the amount of the polymer, and in this case the amount of the polyacrylamide is 3.5 to 9%, a %range that is encompassed within the claimed range. Furthermore, the Lessel declaration argues that the process of making the polyacrylamide hydrogel involves extensive washing, but, although the method claims include the process of bringing together acrylamide and bis-acrylamide, the prior art also does the same by bringing together acrylamide and bis-acrylamide; the claims do not require extensive washing or how many times the hydrogel is washed and how much solvent is used at each wash in order to provide a hydrogel product that may have lower % of acrylamide monomers than the hydrogel of the prior art having amounts of acrylamide that touches points within the claimed range. The declaration is also not effective to remove Pavlyk as a reference in terms of the argument that Pavlyk does not control the prepared hydrogel for residual monomer because the claims are not directed to the process of making the hydrogel product and are not directed to controlling monomer content. The declaration in paragraph (11) is relying on the specification for limitations that are not claimed.

13. B. David Diamond:

14. The declaration under 37 CFR 1.132 filed 6/11/08 is insufficient to overcome the rejection of claims 91-128 based upon 35 USC 103 over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041) as set forth in the last Office action because:

The Diamond declaration opines that the skilled artisan would not have at the time the invention was made presume or reasonably expect that using bulking agent to correct vesicouretal reflux (VUR) would predictably be successful in treating pediatric urinary incontinence with "that bulking agent." The opinion declaration is not effective in overcoming the rejections because generic claims 91, 111 and 115-117 and the claim dependent therefrom are not directed to treating pediatric urinary incontinence. Furthermore, the suggestion by the RU, the Sknar reference, and acceptance by the declaration that, bulking agents have been used to treat VUR and other types of urinary incontinence in children provides a basis for the ordinary skilled artisan to reasonable expect that bulking agents injected into the tube connecting the urinary bladder to the outside would successfully bulk the tube and increase resistance to the flow of urine from the bladder to the outside.

15. D. Ankorina-Stark:

16. The declaration under 37 CFR 1.132 filed 6/11/08 is insufficient to overcome the rejection of claims 91-128 based upon 35 USC 103 over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041) as set forth in the last Office action because:

17. The declaration is centered on the belief at the critical date, a person “knowledgeable of bulking agents would not have been motivated to use polyacrylamide, or would not have

reasonably expected success in using polyacrylamide, as a bulking agent to treat UI, even in view of the documented usage of polyacrylamide hydrogel as a bulking agent to treat VUR, as the Sknar patent." The declaration supports this opinion by citing Kazachkov et al., in Arkh. Patol. 60:58-61 (1998), English-language abstract; De Bree et al., in Arch. Facial Plast. Surg. 6: 204-06 (2004), abstract; Wang et al., in Zhonghua Zheng Xing Wai Ke Za Zhi 19:328-30 (2003), English-language abstract; Xi et al., in J. Biomed. Mat. Res. Pt. A 78A:283-290 (2006); Jordan et al, in Journal of Materials Science: Materials in Medicine, 15:519-522 (2004); all of which show problems with polyacrylamide use, and specifically Xi that reports problems with levels of residual acrylamide monomer. The examiner does not find this opinion persuasive in overcoming the rejections even though supported by reference to show the dangers of using polyacrylamide and levels of residual acrylamide monomer because polyacrylamide hydrogels have been used in biological environments as can be seen in the discussion that follows. While the earliest reference cited is a May-June 1998 reference reporting iatrogenic granulomatous pleurisy after cosmetic application of polyacrylamide hydrogel, it is known in the art that a) polyacrylamide hydrogels have been used as an endoprosthesis around the urethra as disclosed by Annis et al. in US 4,857,041 published Aug. 15, 1989; b) polyacrylamide endoprosthesis have been used in humans according to Pavlyk, US 5798096, published 8/25/1998 having an effective date of Jan. 23, 1997 with the corresponding PCT filed Aug. 12, 1994; and c) composition comprising polyacrylamide hydrogel used in treating urinary incontinence as disclosed by Vogel et al., US 6,335,028 published Jan. 1, 2002 having priority date of March 6, 1998. The declaration further cites Contura as detecting high residual acrylamide monomer levels in the hydrogel of Pavlyk, which Contura attributed to contributing to the negative performance of the

hydrogels and, Contura set out to improve the performance of the polyacrylamide hydrogel by instituting washing steps that significantly reduced residual acrylamide monomer. But, declaring that Contura washed the hydrogel to reduce residual acrylamide monomer in the polyacrylamide hydrogel is not effective in overcoming the rejections of record because the claims are not directed to how the polyacrylamide hydrogel is made and how many times the hydrogel is washed and with what volume of solvent the hydrogel is washed with at each wash to arrive at a polyacrylamide hydrogel having acceptable performance. Furthermore, even if the claims were directed to how a polyacrylamide hydrogel is made, there is no side by side comparison showing the difference in performance (as per the declaration) between a hydrogel having a residual acrylamide monomer of less than 50 ppm and those that have residual monomer levels to the right and left of the less than 50 ppm.

18. E. Roger R. Dmochowski:

19. The declaration under 37 CFR 1.132 filed 6/11/08 is insufficient to overcome the rejection of claims 91-128 based upon 35 USC 103 over Pavlyk (US 5,798,096) in view of RU 2148957 and applicants admission (interview of 2/23/06 and remarks filed 2/27/06) and further in view of Annis et al. (US 4,857,041) as set forth in the last Office action because:

20. The declaration is of the opinion that the skilled artisan in the filed of Urology, knowing the differences between VUR and UI would not have been led by the teaching of the Sknar RU reference to treat UI with polyacrylamide hydrogel by administering the hydrogel to the urethra. However, the declaration appears to ignore the fact that the rejection of the claims is made over a combination of references and not just over the Sknar reference. The rejection is clear that

Sknar is relied upon to show that polyacrylamide hydrogel impedes the flow of urine, the Sknar reference does not categorically say that the polyacrylamide hydrogel would only impede the flow of Urine from the ureter back to the kidneys. Since polyacrylamide hydrogel impedes flow of urine when administered to the ureter, it is reasonable to expect that polyacrylamide hydrogel administered to the ureter would also successfully impede the flow of urine.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 91-128 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-14, 16-18, 20-42 of copending Application No. 11/469,213 (US 20070020226) according to the rejections of record and modified to reflect the new claims as reiterated herein below. Although the conflicting claims are

not identical, they are not patentably distinct from each other because co-pending claims 1, 18, 36 treat incontinence with polyacrylamide hydrogel where the incontinence is urinary incontinence. The claims dependent on 36 further describe the hydrogel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

23. Applicant's arguments filed 6/11/08 have been fully considered but they are not persuasive.

24. Applicant had requested that the rejection be held in abeyance until all remaining rejections and objections have been withdrawn and allowable subject matter has been indicated. This is not persuasive because the provisional obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

No claim is allowed.

Suggestion:

It was suggested to applicant, as was suggested previously and as stated on page 8 of applicant's remarks of 10/20/06, that the hydrogel be injected into the urethra at 0.5 cm distally from the neck of the bladder to overcome the art, explanation of why that position provides unusual and unexpected result may be necessary. Please note that Vogel injects hydrogel of the type claimed into the urethra.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618